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HL

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/945,425 10/21/97 CEDERBERG

C 1103326-282

HM12/1210

EXAMINER

WHITE & CASE
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2787

DESAI, R

ART UNIT	PAPER NUMBER
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10

1612

DATE MAILED:

12/10/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/945,425	Applicant(s) Cederberg Christer et al
Examiner Rita Desai	Group Art Unit 1612

Responsive to communication(s) filed on Nov 1, 1999

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1-11, 15, 16, and 18-25 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

Claim(s) _____ is/are allowed.

Claim(s) 1-11, 15, 16, and 18-25 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 6 & 7

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

Applicants arguments regarding the restriction/ lack of unity is not found to be convincing.

Unity requires a special technical feature and a common core.

Applicants common core -s=o- is not novel. Restriction/Lack of Unity is made FINAL.

Applicant must cancel the non-elected subject matter in their response. Applicants preserve their right to file a divisional on the canceled non-elected subject matter in due course, without prejudice.

The claim 1 rejected under 35 USC 112 is withdrawn since the applicant has amended their claims.

The claims 1-11,15, 16,18 and 19 rejected under 35 USC 102 as being anticipated by Bergstrand et al still stands. See whole document specially lines 33-38 of column 5. Multiple layered tablets inherently would give an extended release of dosage. See Sachs et al US 5,945,124, lines 30-35 of column 3. Thus with an extended release it is inherent that it would give an extended blood plasma profile.

Claims 1-11, 15,16,18 and 19 rejected under 35 USC 103 as being unpatentable by Berstrand et al still stands. Applicants arguments have been fully considered are not found to be convincing.

New Rejections

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Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11, 13, 19-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Bergstrand et al US 5,753,265.

Berdstrand et al '265 discloses the compounds and their use as H⁺K⁺-ATPase inhibitors, with an extended release to extend the blood plasma profile. See formula I ,lines 20-60 of col. 1, lines 33-63 of col. 5, lines 9-15 of col. 7. Also see whole document.

Claim Rejections - 35 USC § 103

Claims 1-11,13, 18-25 are rejected under 35 U.S.C. 103 as being unpatentable by Bergstrand et al US 5,753,265, in view of Sachs et al, US 5,945,124, Pharmaceutics, Science of Dosage Form Design. And T. Lind et al, Gut 1983, pages 270-276 and T. Lind et al , pages 1259-1266. Bergstrand teaches the compounds , oral formulations, and method of using the compounds of the claimed invention. Except that it does not specifically mention extended blood plasma profile. See whole document specially lines 33-38 of column 5. But, multiple layered tablets inherently would give an extended release of dosage. See Sachs et al US 5,945,124, lines 30-35 of column 3. Thus with an extended release it is inherent that it would give an extended blood plasma profile.

A person of skill in the art would have been motivated to use extended release tablets, or other formulation to obtain an extended blood plasma profile, since it is well known that the effect of

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H₊,K₊ATPase inhibitors diminishes after a few hours . See references T. Lind et al , pages 1259-

1266, Tore Lind et al , Effect of Omeprazole, Gut. 1983, pages 270-276.

Sach et al teaches pantoprazole, which is one of the H₊,K₊ATPase inhibitors. It would have been obvious to use the same concept for other H₊,K₊ATPase inhibitors like omeprazole.

The Science of Dosage Form Design from Pharmaceutics teaches different ways and pros and cons of making and using sustained release tablets and formulations. See page 315 of the article.

The compounds according to Berstrand along with the teachings of Sach's'124 , one of skill in the art would extend the principles of pantoprazole, to other H₊,K₊ATPase inhibitors, like Omeprazole etc.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, will the shortened statutory period expire later than three months from the mailing date of this final action.

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. Desai whose telephone number is (703) -305-1868. The examiner can normally be reached on Monday to Friday from 8.00 am to 4.30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the supervisor, Mr. John Kight, can be reached on (703) 308-0204.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235 .

R.D.

Dec. 8th. 1999.

Alan L Rotman
ALAN L. ROTMAN
PRIMARY EXAMINER